

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS**

UNITED STATES OF AMERICA,  
ex rel. IVEY WOODARD,

Plaintiffs/Relators,

v.

DAVITA, INC.,

Defendant.

)  
)  
)  
)  
)  
)  
)  
)  
)  
)  
)

**Civil Case No. 1:05-CV-00227**

**FOURTH AMENDED COMPLAINT**

Relator, Ivey Woodard, through his attorneys and on behalf of the United States of America, hereby files this Fourth Amended Complaint against Defendant, DaVita, Inc., and alleges as follows:

**I. NATURE OF THE CASE**

1. This action, brought pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, *et seq.*, and the Fraud and Abuse Statute, 42 U.S.C. § 1320, *et. seq.*, arises from DaVita, Inc.'s ("DaVita") fraudulent schemes in connection with its utilization of and billing practices for the drug Epogen (also referred to as "EPO"). Specifically, Relator, Ivey Woodard ("Relator" or "Woodard"), complains of DaVita's false certifications in its billing records and certifications to the Federal Government pertaining to (1) DaVita's billing of the United States for the administration of overfill that it received for free; (2) DaVita's over-administration of Epogen without regard to medical necessity or patient need; and (3) its failure to account to the United States for its receipt of discounts, rebates, and prohibited remuneration received from Epogen's manufacturer. DaVita's misconduct resulted in its unjust and illegal enrichment at the expense of the United States. Through this action,

Woodard seeks to recover damages and civil penalties arising from DaVita's false and improper claims that were submitted to the United States for payment under its healthcare programs.

## **II. THE PARTIES**

2. Relator, Ivey Woodard, is a resident of Signal Mountain, Tennessee. Woodard was employed by Amgen, Inc. ("Amgen") in various capacities between 1990 and September 2001. In those capacities, he regularly visited DaVita's facilities, and he regularly interacted with its agents and employees. Amgen is a biotechnology company that develops, manufactures, and markets human therapeutics based on advances in cellular and molecular biology. During the time period at issue, Epogen was Amgen's "blockbuster" product and had a sales volume in excess of \$2 billion per year.

3. From 1990 through June 1996, Woodard was a professional sales representative at Amgen's Houston, Texas facility. In that capacity, Woodard was responsible for sales and marketing in a region that included Livingston, Cleveland, Lufkin, Nacogdoches, Bryan, Kingwood, Humble, and a large portion of Houston. From 1992 through June 1996, Woodard routinely visited DaVita's facility in Lufkin, Texas and met with its nurse manager, anemia manager, and/or clinic director about the facility's maximization of profit through the Epogen administration, overfill usage, and other discounts and financial support. Woodard had similar meetings at DaVita's Livingston facility from approximately 1993 to June 1996, and also several such meetings at its clinic in Cleveland, Texas during mid-1996.

4. From June 1996 through December 1999, Woodard was employed as one of Amgen's national accounts managers, a title which previously had been "government

payor relations representative.” As a national accounts manager, Woodard assisted Amgen sales representatives with increasing Epogen sales in a seven-state region in the Southeast United States: Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, and South Carolina. During the three-year period that he was a national account manager, Woodard accompanied sales representatives into many of DaVita’s facilities in that region. Woodard specifically recalls addressing Epogen usage (including increased usage of Epogen for patients with hematocrit levels above 36%), overfill utilization, and discounts in meetings with DaVita’s clinic administrators, medical directors, directors of nursing, anemia managers, and/or nursing staff (particularly nurses who were specifically trained in the drawing of Epogen overfill, often referred to as “Epogen nurses”) at DaVita’s facilities in Atlanta, Georgia (including clinics known as DaVita Atlanta Dialysis,<sup>1</sup> DaVita Atlanta West Dialysis, and DaVita Buckhead Dialysis); Miami, Florida; Orlando, Florida; Ocoee, Florida; and numerous others. These were not unique, one-time conversations about a one-time fraudulent event; to the contrary, Woodard’s meetings with DaVita’s personnel, listed above, routinely addressed the subjects that are the basis of this lawsuit and the factual allegations identified below.

5. From January 1, 2000 through September 2001, Woodard was a professional sales representative employed at Amgen’s office in Chattanooga, Tennessee. During that period, Woodard repeatedly visited DaVita Piedmont in Atlanta, Georgia. As detailed below, Woodard frequently spoke with DaVita Piedmont’s clinic administrators, directors

---

<sup>1</sup> Given DaVita’s change of names for the company and its dialysis centers during the time period at issue, Woodard refers to specific facilities by their current names.

of nursing, anemia managers, nurses who had been specifically trained to draw Epogen overfill, and other members of the nursing staff about the subjects of this litigation.

6. As a result of his employment by Amgen, Woodard became aware of the fraudulent acts and practices of DaVita as set forth herein. Woodard was terminated from his employment with Amgen based, in substantial part, upon his unwillingness to carry out the unlawful acts and schemes between DaVita and Amgen that were intended to maximize their profits. The information related in this Complaint is derived from the original, first-hand knowledge and information of Ivey Woodard, which is supplemented by his attorneys' investigation.

7. DaVita, Inc. is a Delaware corporation with its headquarters in Lakewood, Colorado. DaVita is one of the largest providers of dialysis services in the United States. During the time period at issue, DaVita served significantly more than 50,000 patients in 35 states and the District of Columbia. At the time that Woodard initiated this litigation, DaVita had over 611 outpatient dialysis centers and also provided acute inpatient dialysis services in over 350 hospitals across the United States. Those numbers have more than doubled during the pendency of this litigation. By agreement with Woodard's counsel, DaVita has agreed to waive service and to appear through its counsel of record.

### **III. JURISDICTION AND VENUE**

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. §§ 3729-33.

9. In addition, this Court has jurisdiction under the doctrine of supplemental jurisdiction over the state law claims pleaded or which may be pleaded to the extent that these claims arise out of a common nucleus of operative facts.

10. This Court has personal jurisdiction over DaVita because it does business within this District.

11. Venue is proper within this District because DaVita conducts business in this District and many of the acts and practices complained of occurred in this District. Acts proscribed by 31 U.S.C. § 3729 were committed by DaVita in this District. Therefore, within the meaning of 28 U.S.C. § 1391(c) and 31 U.S.C. § 3732(a), venue is proper in this District.

12. Woodard consulted frequently with the clinic administrators and nursing staff at the DaVita Livingston Dialysis Center, and he is aware that the pervasive misconduct at issue occurred in this District. Specifically, Woodard consulted with DaVita's administrators and nurses about Epogen use at its Medicare-certified Livingston Dialysis Center, which provides in-center hemodialysis services with approximately 10 stations at 203 North Houston in Livingston, Texas. In reference to DaVita's over-administration of Epogen, the Livingston Dialysis Center submitted 319 claims in which it administered Epogen to clients who had a three-month average with hematocrit (abbreviated as "Hct") levels of greater than 40.0% for the period of 1995 through 2004. In those 319 claims, DaVita administered approximately 15,111,800 units of Epogen and charged \$151,118 for its services. Additionally, in reference to DaVita's over-administration of Epogen, which is one of the claims addressed below, the Cleveland Dialysis Center in this District submitted 272 claims in which it administered Epogen to clients who had a three-month average of a hematocrit of greater than 40.0% for the period of 1995 through 2004. For those 272 claims, DaVita administered approximately 10,138,500 units of Epogen and charged \$101,385 for its services.

#### **IV. FACTUAL BACKGROUND**

##### **A. Governmental Entities With Financial Interest in this Litigation**

13. The federal Medicare program is a health insurance program administered by the United States and funded by taxpayer revenue. The Medicare program is overseen by the United States Health and Human Services Department. Medicare assists state governments with the payment for medical services to persons over the age of 65 and others who qualify under the Medicare program.

14. The federal Medicaid program is a health insurance program administered by the United States and funded by taxpayer revenue. Similar to Medicare, the Medicaid program is overseen by the United States Health and Human Services Department. Medicaid assists state governments with the payment for medical services to persons who have financial need and qualify for Medicaid coverage.

15. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") is funded by the United States and provides medical benefits to retired members of the military services as well as spouses and children of active duty, retired, and deceased members, as well as reservists who were ordered to active duty for thirty days or longer. CHAMPUS is administered by the United States Department of Defense.

16. The Civilian Health and Medical Program of the Veterans Administration ("CHAMPVA") is funded by the United States and provides medical benefits to spouses and children of veterans who are entitled to permanent and total disability benefits from the Veterans Administration and to widows and children of veterans who died of service-

related disabilities. CHAMPVA is administered by the United States Department of Defense.

17. Medicare, Medicaid, CHAMPUS, and CHAMPVA are collectively referred to herein as the Federal Government.

**B. Statutory and Regulatory Requirements that Provide Bases for Woodard's Claims**

18. Compliance with all "applicable Federal, state, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements" is a condition of the Federal Government's payment for medical care provided by dialysis facilities. 42 C.F.R. § 494.20; 42 C.F.R. § 405.2135.

19. Public health insurance, including the Medicare and Medicaid programs, is a cost-reimbursement system. Recently, the Centers for Medicare and Medicaid Services ("CMS") addressed the subject matter of Woodard's first cause of action and confirmed the Federal Government's "longstanding" policy on reimbursement for costs incurred:

Since [April 1, 2008], we have become aware of situations where manufacturers, by design, include a small amount of "intentional overfill" in containers of drugs. We understand that this "intentional overfill" is intended to compensate for loss of product when a dose is prepared and administered properly. For instance, a hypothetical drug is intended to be delivered at a 0.5 mg dose which must be drawn into a syringe from a vial labeled for single use only. The vial is labeled to contain 0.5 mg of product but actually contains 1.5 mg of product. The additional 1.0 mg of product is included, by design, and is intended to be available to the provider so as to ensure a full 0.5 mg dose is administered to the patient.

Our ASP [average sales price] payment calculations are based on data reported to us by manufacturers. This data includes the "volume per item." . . . . In order to accurately calculate Medicare ASP payment limits under section 1847A [of the Social Security Act], we interpret "the amount in one item" to be the amount of product in the vial or other container as indicated on the FDA-approved label.

It has been **longstanding Medicare policy** that in order to meet the general requirements for coverage under the “incident to” provision, **services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies** (See Medicare Benefit Policy Manual (Publication # 100-02), Chapter 15, Sections 50.3, 60.1.A). Such physicians’ services and supplies include drugs and biologicals under section 1861(s)(2)(A) [of the Social Security Act]. In accordance with this policy, **providers may only bill for the amount of drug product actually purchased and that the cost of the product must represent an expense to the physician.**

We further understand that when a provider purchases a vial or container of product, the provider is purchasing an amount of drug defined by the product packaging or label. Any excess, free product (that is, overfill) is provided without charge to the provider. **In accordance with our policy, providers may not bill Medicare for overfill harvested from containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider.** Claims for drugs and biologicals that do not represent a cost to the provider are not reimbursable, and **providers who submit such claims may be subject to scrutiny and follow up action by CMS, its contractors, and OIG.**

Because such overfill is not included in the calculation of payment limits under the methodology in section 1847A of the Act and does not represent an incurred cost to a provider, we are proposing to update our regulations at 42 CFR part 414 Subpart J to clearly state that Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label. We are also proposing to update our regulations to clearly state that payment for amounts of free product, or product in excess of the amount reflected on the FDA-approved label, will not be made under Medicare.

“Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule,” 75 Fed. Reg. 40039 (to be codified at 42 C.F.R. parts 405, 409, et al.) (proposed July 13, 2010) (emphasis added). The provision of the Medicare Benefit Policy Manual that is referenced in the proposed rule states as follows:

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must:



- Be of a form that is not usually self-administered;
- Must be furnished by a physician; and
- Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

The charge, if any, for the drug or biological must be included in the physician's bill, and **the cost of the drug or biological must represent an expense to the physician.** Drugs and biologicals furnished by other health professionals may also meet these requirements.

Publication # 100-02, §§ 50.3, 60.1.A (rev. Oct. 1, 2003) (emphasis added).

20. Like other governmental providers of healthcare coverage, Medicare does not pay for medical care that is not “**reasonable and necessary** for the diagnosis or treatment of illness or injury.” 42 U.S.C. § 1395y(a)(1)(A) (often referred to as section 1862(a)(1)(A)) (emphasis added). Federal regulations reiterate the requirement that medical care be reasonable and necessary. For example, 42 C.F.R. § 411.15(k) excludes from coverage medical services that are “not reasonable and necessary” for the diagnosis or treatment of illness. Similarly, the Medicare Benefit Policy Manual, 50.4.3.3, dictates that the government should not pay for DaVita's misuse of Epogen: “If medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the carrier excludes the entire charge.”

21. As a longstanding consideration for what is reasonable and necessary, the government has looked to the FDA-approved uses and labeling of drugs. For example, in 1989, the Department of Health and Human Services noted:

We may cover FDA-approved drugs for uses other than those specified on their labeling if the available medical and scientific information indicates that

additional uses are appropriate and accepted in the medical community, **unless the uses are contraindicated on a drug's label.** As a matter of current national Medicare policy, drugs or biologicals approved for marketing by the FDA are generally considered safe and effective for purposes of meeting the "reasonable" and "necessary" criteria of section 1862(a)(1)(A) of the Act **when used for indications specified in their labeling.** In addition, FDA-approved drugs also may be covered when used for indications other than those specified on their labeling as long as neither FDA nor HCFA has specified such use as nonapproved, and any additional **relevant medical and scientific information indicates that the additional uses are appropriate and accepted in the medical community.**

Medicare Program, 54 Fed. Reg. 37239-01 (1989) (emphasis added). The term, "unlabeled or off-label drugs," is defined as "Food and Drug Administration (FDA) approved drugs that are used for indications or treatments not included in the approved labeling. The drug must be **medically necessary** for the treatment of the condition for which it is administered, according to accepted standards of medical practice." 32 C.F.R. § 199.2(b) (emphasis added). "Coverage is limited to those indications for which there is reliable evidence, as defined in section 199.2, sufficient to establish that the off-label use is safe, effective, and in accordance with nationally accepted standards of practice in the medical community. In addition, the off-label use must be reviewed for medical necessity." TRICARE; Off-Label Uses of Devices; Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures, 74 Fed. Reg. 44797-01 (2009). Once again, the Medicare Benefit Policy Manual, 50.4.1, corresponds to the federal regulations and requires that the "[u]se of the drug . . . must be safe."

22. The Federal Government's regulations for coverage of Epogen administration apply to other federal programs for medical care. For example, "CHAMPUS can also consider coverage of unlabeled or off-label uses of drugs that are Food and Drug

Administration (FDA) approved drugs that are used for indications or treatments not included in the approved labeling. Approval for reimbursement of unlabeled or off-label uses requires review for medical necessity, and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the unlabeled or off-label use of the drug is safe, effective and in accordance with nationally accepted standards of practice in the medical community.” 32 C.F.R. § 199.4(g)(15)(i)(A) (note that follows; emphasis added).

23. Medicare coverage exists only for medical services provided safely in accordance with good medical practices. “Benefits may be extended for the allowable charge of those other covered services and supplies described in paragraph (d) of this section, which are provided in accordance with good medical practice and established standards of quality by those other authorized providers described in § 199.6 of this Regulation.” 32 C.F.R. § 199.4(d)(1) (emphasis added).

24. Each year, DaVita submits a cost report known as HCFA-265 to the Health Care Finance Administration. The HCFA-265 report is required from all dialysis facilities that bill to the Federal Government, and the report includes a certification of DaVita’s adherence to federal laws and regulations. The tender of the cost data and the certification in HCFA-265 are conditions of coverage. 42 C.F.R. §§ 405.2138, 413.20(b), 494.180(h)(3).

25. The Fraud and Abuse Statute makes it illegal to knowingly and willfully solicit or receive any type of remuneration, including a rebate, in return for purchasing, arranging for, or recommending any good or service for which the Federal Government may pay in

whole or in part. 42 U.S.C. § 1320a-7b(b)(1) & 7a(a)(7). Section 1320a-7b provides for criminal penalties, while § 1320a-7a provides for civil monetary penalties. Because of these provisions, most rebates and discounts on government-reimbursed items violate the Fraud and Abuse Statutes. If, however, the rebate or discount is properly reported and passed on to the Federal Government, it may fall within a “safe harbor” of protected activity. 42 U.S.C. § 1320a-7b(b)(3)(A).

26. The False Claims Act provides, *inter alia*, that any person who knowingly submits a false or fraudulent claim to the Federal Government for payment or approval is liable to the government for a civil penalty of not less than \$5,500 and not more than \$11,000 for each claim, plus three times the actual damages that the government sustained. 31 U.S.C. § 3729(a). The Act also permits assessment of the civil penalty even without proof of specific damages.

27. For the reasons stated below, DaVita has, in reckless disregard or in deliberate ignorance of the truth or the falsity of the information involved, made or used false or fraudulent records and statements in order to get false or fraudulent claims paid or approved. Such conduct is violative of the False Claims Act. 31 U.S.C. § 3729(a)(1) and (a)(2).

### **C. History of DaVita, Inc.**

28. DaVita is one of the largest providers of dialysis services in the United States. DaVita was formerly known as Total Renal Care, Inc. (“TRC”). In 1994, TRC operated approximately 37 outpatient clinics and 28 inpatient facilities in hospitals. Through aggressive expansion efforts, by the end of 1996, TRC had almost tripled in size – operating 134 outpatient facilities and also servicing 59 management contracts with

hospitals for inpatient services. In November 1997, TRC again doubled in size with the acquisition of its competitor, Renal Treatment Centers. This acquisition was particularly significant because of TRC's efforts to indoctrinate Renal Treatment Centers into TRC's corporate strategy of maximizing the billings for and profits from Epogen. In June 2000, TRC changed its name to DaVita, Inc.<sup>2</sup> By 2004, DaVita had become the second largest provider of dialysis services in the United States, serving more than 45,000 patients through approximately 600 outpatient clinics and 300 hospitals. In December 2004, DaVita reached an agreement to acquire the third-largest provider of dialysis services, Gambro Healthcare, and its 565 clinics. The Gambro acquisition again nearly doubled the holdings of DaVita.

#### **D. Epogen - Generally**

29. Epogen is Amgen's brand name for epoetin alfa, a glycoprotein manufactured through recombinant DNA technology, which stimulates red blood cell production. The same epoetin alfa product, manufactured by Amgen, is also marketed and distributed by Ortho Biotech, L.P., a subsidiary of Johnson & Johnson, under the proprietary name Procrit.

30. Epogen/Procrit was licensed in June 1989, with the following indication: "treatment of anemia associated with chronic renal failure, including patients on dialysis (end stage renal disease) and patients not on dialysis." Under a contractual agreement with Amgen, Ortho Biotech, L.P. has rights to development and marketing of Procrit for any indication other than for the treatment of anemia associated with chronic renal failure.

---

<sup>2</sup> For purposes of this Complaint and regardless of the time frame that is at issue, Woodard shall refer to the corporate entity that was initially Total Renal Care as "DaVita."

Epogen and Procrit have identical labeling information for all approved indications based on development programs conducted by Amgen or Ortho Biotech. Labeling was expanded in April 1993 to include a supplemental indication for the treatment of anemia associated with cancer-related chemotherapy. Amgen had a patent on Epogen until 2005.

31. Epogen is used in the treatment of severe anemia commonly associated with end stage renal disorder (“ESRD”) or kidney disease. The metrics used to determine whether a patient is anemic are hemoglobin (abbreviated as “Hgb”) and hematocrit levels through a blood test. Because nearly all ESRD patients experience anemia as a complication of their illness, DaVita’s dialysis facilities administer Epogen to its patients, most of whom require regular dialysis treatment. As a result, dialysis clinics such as those run by DaVita are the largest volume purchasers of Epogen.

32. Amgen produces and sells Epogen in preservative-free, single-use vials and also in vials with preservatives intended for multiple uses/patients.

33. For the time period at issue, dialysis sessions for the treatment of ESRD were capped by Medicare at a bundled or composite rate. However, the Federal Government paid separately for certain dialysis-related drugs based on the dose and frequency of administration. Epogen and the supplies used to administer it were reimbursed by the Federal Government in addition to the composite rate paid for each dialysis session.

34. Because the Federal Government reimbursed dialysis clinics for ESRD injectable drugs outside of the composite rate, DaVita’s administration of drugs such as Epogen was a source of additional revenue to its dialysis centers. In other words, because it was profiting from the administration of Epogen, DaVita had a financial incentive to maximize the treatments and the dosages of Epogen. In fact, Epogen payments by

Medicare empirically have been the second-largest source of for-profit dialysis facilities' income, estimated to be approximately 25% or more of DaVita's income.

35. Epogen therapy has been the largest single Medicare drug expenditure. In 2004 alone, Medicare paid more than \$1.8 billion for Epogen therapy, which was a 17% increase from the 2003 expenditures. During that same period, Epogen treatments comprised 11% of all ESRD costs to Medicare.

#### **E. DaVita's Capture and Use of Epogen Overfill for Increased Profits**

##### **(1) Purpose of Overfill in Epogen Vials**

36. General guidelines for injections outlined in the United States Pharmacopeia ("USP") require that Epogen vials have an excess volume sufficient to permit withdrawal and administration of the labeled fill volumes. The USP test to determine if a vial meets this requirement specifies that the contents of the test vial be drawn into a dry hypodermic syringe fitted with a 21-gauge needle not less than one inch in length. The contents of the syringe are then discharged, without emptying the needle, into a graduated cylinder. The volume measured cannot be less than the labeled volume.

37. To meet the vial-filling requirement, the USP generally recommends a 0.1 mL overfill for a labeled fill volume of 1.0 mL and a .15 mL overfill for a labeled fill volume of 2.0 mL. Instead, Amgen manufactured and dispensed Epogen with a "target" fill volume of 1.168 mL for a single-dose vials and 2.168 mL for the 2 mL multidose vials. Before the overfill percentages were essentially equalized, multi-use vials were "overfilled" by approximately 12 percent, while the single-use vials were "overfilled" by as much as 25 percent. Overall, Amgen provided an unnecessarily large amount of overfill as an

inducement for the purchase of its product, and not surprisingly, DaVita's clinics almost exclusively purchased the single-dose vials with the larger percentages of available overfill.

**(2) FDA Labels - 1993 and 1999**

38. The 1993 and 1999 FDA Labels, which are perhaps more commonly known as the package inserts, specify that the single-dose 1mL vials of Epogen contain no preservatives. They further specify: "Use only one dose per vial; do not re-enter the vial. Discard unused portions." The vials also are labeled for "single-use only."

**(3) Risks to Patients Caused by Multiple Entries into Single Dose Vials**

39. To avoid potential infection risks to the patient, Amgen's official position is and has been that the Epogen in single-dose vials cannot be pooled and re-used. Instead, the potentially contaminated overfill in single-use vials should be discarded after the single dose has been withdrawn. In undated correspondence with DaVita's clinicians in approximately 2000, Amgen noted:

As supplied, EPOGEN in single dose vials is a sterile solution. Although multidose vials with preservative are available, single dose vials **DO NOT** contain a preservative. Once a syringe has entered a single dose vial, the sterility of the product can no longer be guaranteed. The instructions provided in the labeling for the product under the section 'Preparation and Administration of EPOGEN' state: *'Single-dose 1mL vial contains no preservative. Use one dose per vial; do not re-enter vial. Discard unused portions.'*

(emphasis in original).

40. In other correspondence with clinicians, Amgen noted that it "cannot and will not condone unsafe practices that may be utilized to capture any overfill, such as the pooling of unused portions of the Single-Dose Preservative-Free vials of Epogen."



41. Amgen advised DaVita of the health risks associated with the capturing of overfill. For example, such practices resulted in at least one CDC-reported case of *Serratia liquefaciens* sepsis “in a dialysis unit where EPOGEN had been extrinsically contaminated by personnel during pooling of the overfill of the single use vials.” On a separate occasion, Amgen advised dialysis clinics that it was aware of at least 21 episodes of bacteremia or pyrogenic reactions under similar circumstances.

42. Because of such risks, many states prohibit multiple entries into single-use vials in their pharmaceutical laws and regulations. Under the circumstances, multiple entries into Epogen vials are contrary to the FDA-approved use and also good medical practice.

**(4) Despite its Official Prohibition on Re-entry into Single Dose Vials, Amgen Instructed DaVita on the Financial Benefits of Epogen Overfill**

43. Despite its official position that overfill could not be utilized through a reentry into single dose vials, Amgen sales representatives, including Woodard, and clinical support specialists taught DaVita’s nursing staff to make multiple entries into the single use vials, to extract the overfill, and to administer this “captured” overfill to patients. Amgen sales representatives, such as Woodard, also spoke with DaVita’s clinic administrators about DaVita’s billing of the Federal Government at the regular price for the captured overfill.

44. Amgen’s sales representatives (including Woodard) provided DaVita’s staff with visual aids to show the profit that could be earned by using 10% overfill from Epogen vials. Of the many DaVita clinics in which he worked, Woodard recalls that he used this

type of visual aid in sales meetings with clinic directors, directors of nursing, and/or anemia managers at the following DaVita-owned clinics:

- a. DaVita Lufkin Dialysis Center in Lufkin, Texas in approximately 1992;
- b. DaVita Livingston Dialysis Center in Livingston, Texas in 1993, soon after the clinic opened;
- c. DaVita Cleveland Dialysis Center in Cleveland, Texas in the spring of 1996;
- d. DaVita Atlanta Dialysis in Atlanta, Georgia in approximately 1996;
- e. DaVita Atlanta West Dialysis in Atlanta, Georgia in approximately 1997;
- f. DaVita Buckhead Dialysis in Atlanta, Georgia from about June 1996 through December 1999;
- g. From approximately June 1996 through December 1999 in several DaVita dialysis facilities in Miami, Orlando and Ocoee, Florida; and
- h. DaVita Piedmont in Atlanta, Georgia in 2000.

From 1996 to 2000, as Amgen's national account manager for a seven-state region, Woodard specifically recalls at least three Amgen sales representatives using visual aids in presentations at DaVita clinics to show the profit that could be earned by using 10% overfill from Epogen vials.

45. In part from training by Amgen sales representatives and clinical support specialists, DaVita's dialysis clinics were aware that they could collect the overfill in the single-use vials and use it as a source of substantial amounts of "free" Epogen, which they

would nevertheless bill to the Federal Government as though it came from new vials for which DaVita had paid.

**(5) DaVita's Capture and Use of Epogen Overfill**

46. Since approximately 1992, DaVita instructed its nursing staff to make multiple entries into single-use vials of Epogen to capture the overfill. DaVita combined the overfill from multiple vials to form additional doses of Epogen and the "recaptured," additional doses of Epogen were administered to patients and were billed to the Federal Government as if they came from new vials. Such multiple entries into single-dose vials were a violation of standard medical practice and state laws. The practice also violated the government's conditions of coverage, which require use of medications according to their labels and consistent with good medical practice. Finally, DaVita's billing for Epogen overfill violated the laws requiring that such a windfall – DaVita's receipt and use of "free" Epogen – be passed to the Federal Government.

47. Because of the profit that could be generated from the pooling and selling of Epogen overfill pulled from single-use vials, DaVita, as part of its business model, tracked the volume of "captured" Epogen. In fact, DaVita generated monthly reports that tracked the amount of Epogen captured by its facilities. Such reports demonstrate—with surprising clarity—that DaVita administered more Epogen than it had in its inventory.

48. A report from DaVita's Atlantic region demonstrates the high volume of captured overfill and the over-charging for Epogen to the Federal Government. The report also demonstrates that DaVita's facilities captured, administered, and sold Epogen overfill as a part of a company-wide effort to generate undue income and to mislead CMS and the Federal Government.

Facility	Monthly	Epogen	Usage	Year-to-Date	Epogen	Usage
	Units Administered	Units from Inventory	Volume Captured	Units Administered	Units from Inventory	Volume Captured
Atlantic Stars Region 1	32,811,000	29,878,000	9.82%	205,887,420	187,465,000	9.83%
Atlantic Stars Region 2	44,802,100	41,524,000	7.89%	248,542,200	229,758,000	8.18%
Atlantic Stars Region 3	48,242,300	40,349,000	19.56% (likely inflated by clerical error)	255,146,400	228,184,000	11.82% (likely inflated by clerical error)
Atlantic Stars Region 4	50,018,300	47,750,000	4.75%	173,724,100	162,890,000	6.65%
Atlantic Stars Region 5	43,123,300	40,190,000	7.30%	198,957,800	182,974,000	8.74%
Atlantic Stars Region 6	63,473,600	58,770,000	8.00%	307,413,000	284,700,000	7.98%

49. DaVita's strategic use of overfill in Epogen vials is the only way that DaVita could so consistently administer more Epogen to patients than it had in its inventory. DaVita's careful tracking of Epogen capture by year, month, and facility—combined with the powerful financial incentives to use as much Epogen as possible—indicates its calculated misuse of Epogen for the maximization of profit.

**(6) Observations of DaVita's Corporate Strategy and National Practice of Collecting Overfill**

50. To illustrate DaVita's prolonged and systemic efforts to wrongly maximize its profits off of Epogen administrations, Woodard can point to specific information based on his personal observations as well as what he has subsequently learned in his informal investigation of the claim. For example, on November 27, 2000, Woodard spoke with the director of nursing at DaVita's Piedmont Dialysis Center in Atlanta, Georgia about the

clinic's efforts to collect Epogen overfill.<sup>3</sup> She indicated that the clinic had designated one nurse to draw out the Epogen from single dose vials because that nurse was able to draw the greatest amount of overfill from each vial. The purpose of this practice was for DaVita to maximize its yield from Epogen vials and to generate as much profit as may be possible from the increasing volume of Epogen administrations. The nurse also noted that, in the many corporate meetings that she had attended, DaVita focused on the revenue potential of capturing and administering Epogen overfill.

51. Based on the information that Woodard knew at the time that he initiated this lawsuit and has subsequently confirmed, DaVita's billing for the administration of Epogen overfill was a national practice. A former DaVita employee has confirmed that DaVita's practices were national in scope and remained largely unchanged in the years after Woodard last worked in DaVita's clinics. The DaVita witness was a quality control manager for 17 DaVita clinics on Long Island from 2000 to 2006. In 2006, he was a facility administrator for DaVita Lynbrook Dialysis Center and Freeport Kidney Center, both of which are in New York. Also, from March to September 2008, the witness was the facility administrator for the DaVita South Brooklyn Nephrology Center. The former DaVita employee (hereafter "DaVita's New York QCM/FA") has confirmed that, at the New York clinics with which he is familiar, DaVita continued to capture and bill for overfill at least

---

<sup>3</sup> Woodard chooses not to identify witnesses by name in his complaint, because of a concern for the repercussions and/or pressures on witnesses named in this publicly-filed document. Woodard's Third Amended Complaint was posted on a website related to renal care, and the identification of administrators and/or nurses could negatively affect their employment within the healthcare industry. Woodard is willing to tender the names of witnesses to the Court in camera, and he expects that witnesses will be identified during discovery with DaVita.

through 2008. In fact, DaVita paid bonuses (reportedly 10 to 15% of the amount of billed overfill) to administrators of facilities that maximized their capture of and billing for Epogen overfill.

52. Several of DaVita's former nurses also corroborated what Woodard had previously known about DaVita's use of and billing for overfill. From September 2000 through January 2001, a charge nurse at DaVita Kent Dialysis Center in Kent, Washington observed the routine pooling of unused Epogen from single dose vials and the delivery of that overfill to patients. In New Orleans from November 2003 to June 2004, and in Houston from May 2007 to July 2009, a different DaVita nurse observed that DaVita was capturing Epogen overfill and saving it for later administration. The amount of overfill extracted from the Epogen vials was logged on an "overfill sheet" (whether on paper or electronic, depending on the time frame or clinic). According to DaVita's nurse from New Orleans and Houston, it was common knowledge within DaVita that the company was extracting as much Epogen from each vial as possible because of the company's practice of billing the Federal Government or private insurers for every drop.

53. Over the five years that he worked for Amgen, Woodard also heard similar accounts from clinics' directors of nursing, clinic administrators, anemia managers, and nurses specifically trained in overfill collection (sometimes known within DaVita clinics as "Epogen nurses") about DaVita clinics' collection, use, and billing for Epogen overfill. Conversations about DaVita's administration of and profit from overfill took place at almost every DaVita clinic that Woodard visited, and examples of such facilities include the following locations:

- a. From approximately 1992 to June 1996 at the DaVita Lufkin Dialysis Center in Lufkin, Texas;
- b. From roughly 1993 to June 1996 at the DaVita Livingston Dialysis Center in Livingston, Texas;
- c. In the spring of 1996 at the DaVita Cleveland Dialysis Center in Cleveland, Texas;
- d. From approximately June 1996 through December 1999 at DaVita Atlanta Dialysis in Atlanta, Georgia;
- e. From roughly 1997 through 1999 at DaVita Atlanta West Dialysis;
- f. From about June 1996 through December 1999 at DaVita Buckhead Dialysis in Atlanta, Georgia;
- g. From approximately June 1996 through December 1999 in several DaVita dialysis facilities in Miami, Orlando, and Ocoee, Florida; and
- h. From January 1, 2000 through September 2001 at DaVita Piedmont in Atlanta, Georgia.

54. On a broader scale, Woodard also is familiar with DaVita's efforts to impose its corporate policies for Epogen use on newly-acquired dialysis centers. After DaVita acquired Renal Treatment Centers ("RTC") in November 1997, DaVita and Amgen worked cooperatively to transition the RTC clinics, particularly those in the Southeast United States, to DaVita's corporate strategy of maximizing profit from Epogen use, including the collection of overfill and the increasing of target hematocrit levels related to Epogen administration. When RTC clinics were reluctant or unwilling to comply with DaVita's directives on Epogen use, senior management with DaVita and Amgen met with clinic

administrators and brought those clinics into compliance with DaVita's Epogen-related objectives.

55. The Federal Government did not foresee that outpatient dialysis facilities would attempt to submit Epogen doses that DaVita was receiving at no cost. Therefore, DaVita's outpatient dialysis facilities were not required to submit figures for the Epogen units purchased as well as the units administered on their cost reports. This effectively prevented the Federal Government from tracking DaVita's misuse of Epogen overfill.

**(7) DaVita's Use of Epogen Overfill Conflicts with its Practice of Wasting Other Medications, Such as Zemplar, for which the Federal Government Pays DaVita by the Vial**

56. DaVita's manipulation and use of overfill stands in stark contrast to its practices in the administration of other drugs, such as Zemplar. Not coincidentally, the Federal Government paid DaVita for Zemplar by the vial, as opposed to its payment for Epogen by the dose.

57. With Zemplar and other medicines for which it was paid by the vial, DaVita made no effort to collect overfill or to maximize the utility of each vial of medicine. To the contrary, DaVita decreased dosages and increased the number of treatments. As Woodard was told repeatedly by directors of nursing and anemia managers at many of the clinics in which he worked, DaVita directed that its clinics should discard the unused portion of the vials. This enabled DaVita to maximize its charges for the single-use vials, a practice that conflicts with its misuse of Epogen overfill.

58. DaVita's abusive practices in the administration of drugs, such as Zemplar, illustrate that billing guidelines and profit motives dictate the treatment regimen (including



the frequency and dosage of treatment) of drugs billed separately to the Federal Government.

**F. DaVita's Over-Utilization of Epogen**

**(1) Epogen - FDA Labels**

59. The 1993 FDA Label for Epogen provided the parameters for dosage during much of the time period at issue. The label provided for a starting dose of 50 to 100 units per kilogram for adult patients, administered three times per week (for a 175 pound adult male, this would amount to a starting dosage of between 4,000 and 8,000 units, three times per week). The 1993 FDA Label provided that Epogen should be utilized for adult chronic renal failure (CRF) patients to bring the patient's hematocrit to within a target range of between 30% and 33% (corresponding to a hemoglobin level of 10 to 11). Under the 1993 FDA Label, patients must be monitored regularly, and the dosage must be reduced as the hematocrit level approaches 33% or increases by more than four points in any two week period. When the patient's hematocrit reaches 30 to 33%, the dosage should be decreased by approximately 25 units/kg "to avoid exceeding the target range." The 1993 FDA Label dictated that, as the hematocrit level approaches or exceeds 36%, Epogen treatment should be suspended until the patient's hematocrit decreases to the target range of 30 to 33%, and upon re-initiation, the dosage should be reduced by approximately 25 units/kg.

60. The 1999 FDA Label modified the suggested target range of hematocrit to 30 to 36%. The FDA Label called for a reduction in Epogen dosage as patients' hematocrit levels approach 36% or when hematocrit increases by more than four points in a two-week interval. The 1999 FDA Label specifies:

If the hematocrit is increasing and approaching 36%, the dose should be reduced to maintain the suggested target hematocrit range. If the reduced dose does not stop the rise in hematocrit, and it exceeds 36%, **doses should be temporarily withheld** until the hematocrit begins to decrease, at which point therapy should be reinitiated at a lower dose.

(emphasis added). As with the 1993 FDA Label, the 1999 label required that Epogen dosage must be individualized to maintain patients' hematocrit within the suggested target range.

**(2) Epogen - CMS/DHHS Guidelines**

61. On February 1, 1997, the Department of Health and Human Services (DHHS) issued a Program Memorandum with the following observations and procedure:

ESRD patients with symptomatic anemia considered for EPO therapy should be treated until the hematocrit reaches a target range of 30 - 36%. As the hematocrit approaches 36%, administration of EPO should be reduced temporarily. The dosage of EPO required to maintain target hematocrit levels is subject to individual patient variation and should be titrated according to patient response, with a goal of not exceeding a hematocrit level of 36%.

Effective immediately, but no later than July 1, 1997, begin calculating EPO payments based on a 90-day rolling average hematocrit measurement for ESRD patients whose hematocrit levels are greater than 36%. . . .

If the average of the 90 days of readings is 36.5% or less, pay for EPO. If the hematocrit level exceeds 36.5%, **deny** payment for EPO.

(emphasis in original).

62. In March 1998, having received more complaints and appeals than it could process efficiently, the DHHS modified the procedure on paying for Epogen administration:

Effective for claims for monthly billing periods beginning on or after March 10, 1998, pay claims when the three month rolling average exceeds 36.5 percent. Payment is based on the lower of the actual dosage billed for the current month or 80% of the prior month's allowable EPO dosage.

63. In July 1998, the DHHS issued a new Program Memorandum to its intermediaries and carriers:

When indicated, conduct post-payment review of EPO by looking at a 90-day rolling average of hematocrit levels. Because of the natural variability in hematocrit levels and because we are encouraging practitioners to maintain a hematocrit level within the range of 33 to 36 percent as recommended by the Dialysis Outcomes Quality Initiative, use a threshold hematocrit value of 37.5 percent in targeting aberrant cases. Identify practitioners with an atypical number of patients with hematocrit levels above a 90-day rolling average of 37.5 percent for routine medical review activities, such as educational efforts or pre-payment reviews.

The DHHS continued this directive in subsequent memoranda dated August 16, 2000, July 24, 2002, and September 5, 2003.

64. Effective April 1, 2006, the Centers for Medicare and Medicaid (CMS) implemented a new policy for the monitoring of Epogen usage:

In order to allow for unanticipated increases in hematocrit, Medicare contractors will not be required to initiate monitoring until the hematocrit level reaches 39.0 (or hemoglobin of 13.0). For claims with hematocrit readings above the threshold of 39.0 (or hemoglobin of 13.0), the dose should be reduced by 25 percent over the preceding month in accordance with the FDA labeling.

### **(3) Amgen's Involvement in DaVita's Over-Administration of Epogen**

65. The principal way that Amgen sales representatives increased their sales of Epogen was to increase the dosage of Epogen for existing patients, most of whom were treated on an outpatient basis at dialysis clinics, such as those owned by DaVita. Likewise, the Amgen sales force worked with DaVita to avoid reductions in the application and per-patient dosage of Epogen. Because the scope of treatments with Epogen did not change in the time period at issue, the population of potential Epogen users in the United States did not increase greatly. Unlike the use of many other drugs, Epogen sales could not be increased by marketing to a wider audience. Therefore, under the circumstances and as

detailed below, Amgen sales representatives, such as Woodard, and clinical support specialists called upon DaVita and assisted its facilities with increasing the frequency and dosage of Epogen administrations.

66. By no later than 1994, Amgen was working with its sales representatives to increase the utilization of Epogen. That year, Medicare reduced its reimbursement rate for Epogen. In a memorandum to its sales representatives and district managers, Amgen addressed the impact of the reduction in profits caused by Medicare's lowering of the reimbursement rate:

Due to your efforts many of our customers are prepared and understand the economic impact of Anemia management. The reduced margins reflected in their payments will reinforce the need now more than ever to dose appropriately to achieve the target Hct. This increase in utilization will in turn provide additional revenues to their centers.

On the other hand, there are providers who will view this reduction in their margins as a signal to reduce Epogen usage.

Our sales professionals can 'make the difference' on the way their providers react to this change.

As we visit our customers over the next month be on the look out [sic] for:

- Dose reducing protocols
- Dose withholds
- Patients not achieving target Hct.

These actions may be an indication that our customers are unaware of the 'connection' between higher Hcts, better outcomes, and increased revenues that can only be achieved through appropriate utilization of Epogen therapy. This would be a perfect opportunity to demonstrate the financial impact of achieving the target Hct.

67. Through training, review of patient records, and the drafting of treatment protocols, Amgen taught DaVita's facilities about the "increased revenues" and "financial impact" arising from the increased utilization of Epogen.

**a. Amgen's Training of DaVita Personnel**

68. Beginning in roughly 1996, Amgen provided "anemia management training" and support to DaVita's staff in return for using Epogen. In addition to providing valuable and necessary training to DaVita's staff, as detailed in Section IV.H., below (paragraph 135), Amgen used the platform to advocate its business model of maximizing Epogen usage for profit to both DaVita and Amgen.

69. Amgen's training of DaVita administrators and nursing staff was one of the principal methods by which DaVita educated its staff on a systematic upward manipulation of Epogen usage levels, including how to manipulate the system and maximize the use of Epogen. For example, in approximately 1999, Amgen led a national educational initiative in which its speakers instructed DaVita personnel to calculate hematocrit levels from more-stable hemoglobin readings, instead of using measured hematocrit levels, which are more likely to fluctuate over a short period of time. As Woodard witnessed and subsequently corroborated through an Amgen corporate account manager for New York for the period from 2003 to 2005, DaVita's nursing staff was trained to use hemoglobin levels and to calculate hematocrit levels in a way that kept more patients within ranges acceptable for the continued receipt of Epogen.

70. Woodard has confirmed that education seminars continued after his departure from Amgen. For example, a registered nurse and clinical support specialist continued to provide training to DaVita's personnel, including training through Amgen's Anemia Management Institute ("AMI"), from 2000 through 2003. The witness worked from January 2000 through early 2003 as a clinical support specialist primarily at clinics along the gulf coast in Louisiana and Mississippi. In early 2003, the witness' title changed from

being a clinical specialist educator to a professional service specialist, which included more of a sales component and became less education oriented, and she then worked along the gulf coast in Louisiana and East Texas. Confirming what Woodard recalls, the AMI training took place at local hotels, and clinical support specialists, including the witness, had a presentation that was focused on ways to help nurses and doctors utilize Epogen. With her new title, the training provided by the witness was supposed to address the benefits of Epogen, rather than the use of Epogen as a component for treating the patient's best interests. For instance, in early 2003, the clinical support specialists' presentation included case studies with examples of patients who were not responding to Epogen and were ultimately taken off of the medication. Clinical support specialists were asked to remove those case studies from their presentation, and although she believes that others complied with the request, the witness refused.

71. In addition to anemia management seminars, Amgen also trained DaVita nursing staff through individual discussions. Amgen's clinical support specialists and, to a lesser extent, its sales representatives taught DaVita's nursing staff how to identify patients who had hematocrit levels that were below DaVita's targeted range and also to justify increased Epogen prescriptions.

72. While an Amgen sales representative and/or national account manager, Woodard routinely witnessed DaVita's cooperation with Amgen for the training of nursing staff to increase Epogen prescriptions. This was not a one-time occurrence or limited to a particular DaVita clinic. To the contrary, Woodard witnessed DaVita's corporate strategy on a nationwide basis to increase Epogen usage. DaVita's focus upon the training of staff

to increase Epogen usage was prevalent at every DaVita clinic in the eight states that Woodard worked, including the following locations:

- a. From approximately 1992 to June 1996 at the DaVita Lufkin Dialysis Center in Lufkin, Texas;
- b. From roughly 1993 to June 1996 at the DaVita Livingston Dialysis Center in Livingston, Texas;
- c. In the spring of 1996 at the DaVita Cleveland Dialysis Center in Cleveland, Texas;
- d. From approximately June 1996 through December 1999 at DaVita Atlanta Dialysis in Atlanta, Georgia;
- e. From roughly 1997 through 1999 at DaVita Atlanta West Dialysis;
- f. From about June 1996 through December 1999 at DaVita Buckhead Dialysis in Atlanta, Georgia;
- g. From approximately June 1996 through December 1999 in several DaVita dialysis facilities in Miami, Orlando and Ocoee, Florida; and
- h. From January 1, 2000 through September 2001 at DaVita Piedmont in Atlanta, Georgia.

Similarly, from 1993 through 2002, an Amgen sales representative at DaVita's dialysis centers in Dunedin and Largo, Florida witnessed Amgen's training of DaVita nursing staff on how to maximize Epogen usage.

**b. Amgen's Review of DaVita's Patient Charts**

73. Another significant means of auditing and increasing Epogen usage was through Amgen's access to DaVita's confidential patient information. As Woodard

witnessed, Amgen district managers in the Southeast region, including those out of Atlanta, Birmingham, Miami, and Tampa, regularly instructed sales representatives and clinical support specialists to increase Epogen sales through review of confidential patient charts or patient-specific data without the patients' knowledge or consent, in violation of the patients' privacy rights granted by 42 C.F.R. § 405.2139, 42 C.F.R. §§ 494.70(a)(3), (4) and 494.170(a), and state laws. The purpose of the chart reviews was to determine the dosages administered to the patients in particular ranges of hematocrit and, by learning the clinics' practices, assist them in increasing Epogen dosages.

74. To carry this out, Amgen sales representatives approached DaVita's personnel with access to and authority over patient charts. Most often, the person with control of patient charts was the facility's director of nursing ("DON"). Frequently, clinic DONs allowed Amgen sales representatives to review patient charts "as is." That is, the DON simply turned over the charts or printouts to the Amgen representative for an unfettered review of the chart. In other instances, DONs crossed out patient names before turning over patient charts. Sometimes, instead of reviewing charts in person, the Amgen sales representatives arranged for an Amgen clinical support specialist to conduct the chart review.

75. At certain of DaVita's clinics, the DONs resisted allowing Amgen sales staff to review patient charts. When that happened, the Amgen representatives were trained to enlist the aid of the clinic administrator, who understood that the Amgen chart reviews were intended to instruct DaVita nursing staff on how to maximize Epogen usage and to increase the sales and profitability of the DaVita clinic. Often, DaVita's clinic administrators instructed the DON to allow chart reviews by Amgen. When these direct efforts to obtain



confidential medical records failed, the next recourse was for Amgen's sales representative and/or clinical support specialist to advise his or her superior, either the Amgen district sales manager or the regional sales manager. Amgen's management then contacted higher-up authorities on the "business side" of the clinic and arranged for the Amgen sales representative or clinical support specialist to have access to the clinic's patient charts. As detailed below, Woodard repeatedly observed these practices by DaVita's DONs and clinic administrators.

76. Once the Amgen sales representative or clinical support specialist obtained access to patient charts or patient-specific data, the goals were simple and straightforward: (1) maximize the frequency and dosage of Epogen treatments for as many patients as possible, and (2) continue Epogen treatments even after patients' hematocrit levels were above 36%, without regard to medical need and/or good medical practice. This practice increased Amgen's sales revenue while, at the same time, increasing profits at DaVita's clinics. DaVita profited from each Epogen administration, because of the "spread" between DaVita's purchase price and the Federal Government's reimbursement rate. Further, as detailed in Section IV.G. below, DaVita obtained volume discounts by increasing sales, further increasing its spread and, consequently, its profits. Thus, with respect to increasing Epogen usage, the financial interests of Amgen and DaVita's clinics were aligned.

77. Even though the FDA label set out the target hematocrit level of between 30% and 36%, DaVita's clinic administrators, DONs, and nursing staff, with the assistance and training by Amgen sales representatives, were instructed to push hematocrit levels above the target range. As part of his required tactics to increase sales, Woodard taught—at Amgen's behest—DaVita administrators and nursing staff to increase the clinics'

Epogen usage by driving patients' hematocrit levels above 36%. In his dealings with DaVita clinic administrators, DONs, and anemia managers, and in his review of patients' records, as detailed below, Woodard saw that DaVita followed through with Amgen's recommendations of increasing Epogen dosage.

78. DaVita's systematic increasing of hematocrit levels was brought about through higher Epogen dosages and uninterrupted treatments, neither of which was supported by scientific research nor permissible under the FDA Label for Epogen. Higher Epogen doses, of course, enabled DaVita to bill more Epogen doses to the Federal Government and qualified it for greater volume discounts from Amgen. Both the increase in sales and the increase of discounts and rebates, increased DaVita's profit from Epogen.

79. The sole "basis" for striving for these higher hematocrit levels was that most fiscal intermediaries for the Federal Government allowed for Epogen reimbursement at hematocrit levels of 36% to 37.5% and above without running a substantial risk of additional review. As the Amgen sales staff and DaVita's clinics knew, only when hematocrit levels reached 40% or above was there a "red flag" with these intermediaries. But, even then, the Federal Government would pay once the usage was "justified" for a given treatment regimen, regardless of an individual patient's diagnosis or medical necessity. Amgen sales representatives and/or clinical support specialists provided a list of reasons that could be used by DaVita's clinics to justify a hematocrit level of 40% or above (*i.e.*, the coding of "angina," a relatively subjective diagnosis, was a Medicare-accepted justification). Woodard used such a list as part of his normal sales practices at DaVita Lufkin Dialysis Center, DaVita Livingston Dialysis Center, and DaVita Piedmont. Additionally, as a part of his work as a national account manager working in DaVita's clinics

in a seven-state region until December 1999, Woodard frequently witnessed the use of the chart justifying hematocrit levels of 40% or greater. Therefore, in the event that a fiscal intermediary reviewed the Epogen treatments of a patient with a hematocrit above the target range, DaVita's nursing staff and administrators had been trained on the "proper" ICD-9 code to use. Also, Woodard and the sales representatives in his region provided draft letters with language that the Federal Government considered appropriate justification for exceeding recommended dosages to DaVita's facilities.

80. In Woodard's experience, although doctors at DaVita's clinics ultimately were required to "sign off" on all dosage changes, they typically signed stacks of orders presented to them by the medical staff, either without knowledge of, or without regard for, the fact the chart review and change orders had been prepared or dictated by Amgen sales representatives and/or clinical support specialists with the approval of DaVita's staff. Woodard has subsequently learned that his experience is consistent with DaVita's practices outside of the Southeast United States. For example, DaVita's New York QCM/FA has confirmed that, at least until 2008, DaVita had a "stranglehold" on the physicians practicing in its New York-area clinics and that the doctors practicing in those clinics would prescribe Epogen in accordance with DaVita's protocols or otherwise receive a call from the clinic's chief medical officer.

81. Relator Woodard is personally familiar with these standard practices at DaVita's clinics and, more generally, the cooperative efforts between Amgen and DaVita to maximize the administration of Epogen. While an Amgen sales representative and/or national account manager, Woodard routinely visited DaVita clinics and met with directors of nursing, anemia managers, and/or clinic directors about the methods for increasing

Epogen administration as specified above. Notwithstanding DaVita's all-pervasive practices, Woodard specifically remembers discussing these matters, conducting anemia management training, and/or reviewing patient charts at the following locations:

- a. From approximately 1992 to June 1996 at DaVita Lufkin Dialysis Center in Lufkin, Texas;
- b. From roughly 1993 to June 1996 at DaVita Livingston Dialysis Center in Livingston, Texas;
- c. In the spring of 1996 at DaVita Cleveland Dialysis Center in Cleveland, Texas;
- d. From approximately June 1996 through December 1999 at DaVita Atlanta Dialysis in Atlanta, Georgia;
- e. From roughly 1997 through 1999 at DaVita Atlanta West Dialysis;
- f. From about June 1996 through December 1999 at DaVita Buckhead Dialysis in Atlanta, Georgia;
- g. From approximately June 1996 through December 1999 in several DaVita dialysis facilities in Miami, Orlando and Ocoee, Florida; and
- h. From January 1, 2000 through September 2001 at DaVita Piedmont in Atlanta, Georgia.

82. Even though Woodard opposed the practice, he estimates that he conducted anemia management training or chart reviews at approximately 25% of the clinics for which he was responsible because of pressure from his supervisor. At numerous meetings with his supervisors, he was castigated because this percentage was so low and contrary to Amgen's practice. According to Amgen senior management and corroborated by Woodard

in conversations with other Amgen representatives, approximately 50% to 70% of DaVita's clinics permitted Amgen sales staff to conduct chart reviews.

83. Additionally, Woodard is aware that other Amgen sales representatives witnessed similar events. For example, an Amgen sales representative at DaVita's dialysis centers in Dunedin and Largo, Florida from 1993 through 2002, witnessed the "incredible amount of patient information" that Amgen sales representatives and/or clinical support specialists received from DaVita's staff. That representative, similar to Woodard, is aware that Amgen's clinical support specialists, in particular, would conduct a "sit down" with DaVita's nursing director to review medical records and determine which patients could be receiving more Epogen.

**c. Amgen's Assistance in Writing DaVita Protocols for Epogen Administration**

84. Another related method by which DaVita manipulated Epogen usage at its dialysis clinics was by allowing Amgen to write the clinics' internal protocols for Epogen usage. Amgen seized upon the opportunity to create DaVita's protocols, because of the opportunity to increase Epogen usage. In fact, Amgen considered the benefit to be so substantial that it developed a computer program that its sales representatives and/or clinical support specialists could utilize in preparing internal protocols for clinics. Woodard participated in the design of protocols for Epogen usage in DaVita's clinics and/or used this type of program during sales calls on renal clinics, including DaVita Lufkin Dialysis Center, DaVita Livingston Dialysis Center, and DaVita Piedmont. Further, based on his continued contact with sales representatives and clinical support specialists while a national account manager, Woodard is aware that Amgen continued to design protocols for DaVita at

dialysis clinics in Atlanta and at many other clinics in the seven states that he supervised from June 1996 through December 1999.

85. Although Epogen's FDA Label in 1999 specified 30 to 36% hematocrit as the target range,<sup>4</sup> DaVita's protocols under the Amgen program encouraged substantially higher Epogen use than the clinics would have dictated in independently created protocols. The higher Epogen use set forth in the protocols was driven by the desire to achieve higher revenue, not by patient need, and without regard to patient benefit. As confirmed in research studies, the more aggressive dosing of Epogen recommended by DaVita was the likely explanation for the "over-utilization" of Epogen in the DaVita chains as compared to other for-profit dialysis facilities.

86. With input from Amgen as previously noted, DaVita designed protocols to increase its usage of Epogen. Examples of DaVita's protocols included the following provisions:

- Once a patient's hematocrit level is greater than 36%, this constitutes the beginning of the maintenance phase, and the current dosage should be decreased ten percent. Actual dose after adjustment may be rounded to the nearest 100 units (i.e., 3850u rounded to 3900u).
- Subsequent decreases of ten percent or increases of 25% can be made every four weeks to move and maintain hematocrit within the acceptable range of 33 to 36%.

---

<sup>4</sup> As previously noted, the 1993 FDA Label for Epogen specified a target range for hematocrit at 30 to 33%.

- With proper adjustment, Epogen should be held only if hematocrit is greater than 39.9% and there is no medical justification to maintain a higher level. Weekly monitoring of hematocrit is appropriate at this time.

87. DaVita protocols were not consistent with CMS guidelines and FDA label indications for Epogen usage. For CMS and the FDA, the label indications were to target hematocrit at 30 to 36% and to reduce the Epogen dosage as hematocrit approaches 36%. The FDA Label indicates that dosage should be decreased by 25% before the patient's hematocrit level reaches 36%. In DaVita's protocol, on the other hand, Epogen usage would not be decreased until after the patient's hematocrit exceeds 36%, and at that point, dosage should only be decreased by ten percent. If the patient's hematocrit drops below 36%, DaVita's protocol calls for increased dosages by 25%; this strongly indicates that DaVita's intention is to keep hematocrit levels above 36%. In contrast to DaVita's protocol of quickly increasing dosage, its protocol does not call for a 25% decrease in dosage until hematocrit levels reach 40% and only if no medical justification can be noted for a continuation of treatment. Again, this is contrary to the package insert and FDA instructions for Epogen usage. Having trained DaVita's staff and having reviewed DaVita patients' medical files, Woodard knows that the requirement of "medical justification" was contrived by DaVita as a nominal impediment to Epogen administration. As Woodard witnessed routinely as a national account manager in DaVita clinics and later as a sales representative in DaVita's Piedmont Dialysis Center, DaVita's staff was instructed on how to code files for continued Epogen usage, was encouraged to continue the administration of the drug, and routinely caused their patients to have hematocrit levels in excess of 40%.

88. While these protocols may have been created under the guise of “patient safety” or “medical necessity,” they in fact eschew these goals in favor of increasing Epogen usage for DaVita’s financial gain. Without question, permitting Amgen sales representatives and/or clinical support specialists to create the protocols governing the very drug that Amgen sold seriously undermines any argument that the protocols had patient safety or medical necessity as their bases.

89. Whether developed in-house or by Amgen’s sales representatives or clinical support specialists, DaVita designed protocols to maximize Epogen use without regard to medical necessity. Such protocols were contrary to the FDA label and CMS guidelines and were potentially harmful to DaVita’s patients. In fact, there were at least 21 documented cases of bacteremia or pyrogenic reactions that the Centers of Disease Control attributed to the re-entry of Epogen single-dose vials. Relator Woodard, as an Amgen sale representative and later as a national account manager, is personally familiar with the fact that Amgen sales representatives assisted in the preparation of DaVita clinics’ protocols for Epogen administration. Although such assistance was pervasive at most of DaVita’s clinics, Woodard specifically recalls Amgen having a role in the preparation of protocols for Epogen at the following locations: Lufkin, Texas; Livingston, Texas; Cleveland, Texas; Atlanta, Georgia; Miami, Florida; Ocoee, Florida; and/or Orlando, Florida.

90. Woodard also has confirmed that the preparation of protocols existed in regions outside of the Southeast United States. For example, DaVita’s New York CQM/FA has confirmed that Amgen was writing the protocols for use of Epogen in his New York facilities until approximately 2004.



91. Through anemia management training, chart reviews, and the drafting of protocols, DaVita and Amgen met their financial goals of maximizing Epogen usage without regard to medical necessity. Based on Woodard's experience while working at Amgen and in adjusting patients' Epogen levels, DaVita administrators and nursing staff did not take into account the individualized circumstances of the patient. Furthermore, they did not take into account whether, for a particular patient, there would be medical benefits resulting from an increase in dosage to levels beyond the target range. Instead, the sole consideration was how to increase the dosage. Thus, with encouragement from Amgen, DaVita's nursing staff regularly administered Epogen well beyond the recommended target range of hematocrit levels between 30% and 36%.

**(4) Studies Do Not Support the Use of Epogen to Increase Hematocrit Levels Above 36%**

92. Scientific studies have repeatedly found that ESRD patients show an increase in adverse effects and/or no medical benefit from the normalization of hemoglobin/hematocrit levels. In the trials that supported the original approval of Epogen and Procrit, evidence was presented of an increased risk of thrombotic events, such as severe or catastrophic cardiovascular adverse events. Several years later, researchers found that the targeting of higher hematocrit levels than required for avoidance of transfusion caused an increased risk of fatal cardiovascular events and impaired survival. By the time of FDA-approval of the 1999 label, it referenced medical research findings that Epogen usage for patients with a maintained hematocrit level at  $42 \pm 3\%$  resulted in a statistically-significant increase in the risk of mortality.

93. Researchers have repeatedly found that there is no additional benefit in the quality of life for increasing hematocrit levels above 36%. Moreover, having found that

target hematocrit levels of approximately 40% are associated with poorer outcomes and increased risks among patients with anemia caused by chronic kidney disease, researchers concluded that target hematocrit levels should not be higher than 36% and that Epogen should be discontinued, not merely reduced, when patient hematocrit levels reach 39%.

**(5) For-Profit Dialysis Facilities Administer the Highest Epogen Dosages and Target Higher Hematocrit Levels than Not-For-Profit Facilities**

94. In a study published in the Journal of the American Medical Association in April 2007, researchers and medical doctors found that patients in for-profit dialysis facilities, such as those owned by DaVita, “were consistently administered the highest doses of epoetin regardless of anemia status.”<sup>5</sup> Based on empirical data on 159,522 Medicare-eligible ESRD patients collected from the U.S. Renal Data System, the study found that “[d]ifferent epoetin dosing patterns suggest that large for-profit chain facilities used larger dose adjustments and targeted higher hematocrit levels.”<sup>6</sup>

95. Studies have found that for-profit facilities, such as those owned by DaVita, continued to increase Epogen dosages in patients who had reached the hematocrit target of 33%. The studies further noted that for-profit facilities commonly increased Epogen dosage until their patients’ hematocrit had reached the target of 36%. Based on empirical data, this “overshooting” of the recommended hematocrit target was significantly more prevalent in for-profit chain facilities than in not-for-profit chain facilities.

---

<sup>5</sup> Dialysis Facility Ownership and Epoetin Dosing in Patients Receiving Hemodialysis, M. Thamer, PhD, et al., JAMA, April 18, 2007, 297: 1667.

<sup>6</sup> *Id.* at 1667.

96. Despite the large differences in Epogen dosages and treatment regimens between for-profit and not-for-profit facilities, the study found that most not-for-profit facilities meet CMS performance goals (*i.e.*, 70% of patients having a hematocrit level in excess of 33%).

**(6) DaVita's Records Demonstrate the Over-Utilization of Epogen, Particularly at Hematocrit Levels Above 36%**

97. DaVita's unnecessary administration of Epogen on patients with hematocrit levels above the target range grew exponentially from 1995 through 2004. During that period, for patients receiving Epogen despite a three-month rolling average hematocrit ("a rolling average hematocrit") at or above 37.5%, DaVita's billings for Epogen to the Federal Government's Medicare program grew from annual sales of \$858,082 to \$87,669,999 (an increase of 10,216%). Similarly, for patients with a rolling average hematocrit above 40%, DaVita's billings for Epogen to Medicare increased from \$204,372 to \$30,290,083 (an increase of 14,821%) during that same ten year period.

98. DaVita also saw exponential growth during certain years. From 1998 to 1999, Davita's claims and billings for Epogen where the patient's rolling average hematocrit was in excess of 37.5% increased from \$7,915,932 to \$30,202,666 (an increase of 282%). Similarly, from 2003 to 2004, DaVita's Epogen billings to Medicare increased from \$61,489,247 to \$87,669,999 (an increase of 43%).

99. Likewise, Davita's claims and billings for Epogen in which the patients' rolling average hematocrit levels were in excess of 40% increased from \$2,159,613 to \$9,456,830 from 1998 to 1999 (an increase of 388%), and from \$20,215,884 to \$30,290,083 from 2003 to 2004 (an increase of 50%).

100. In 1998, approximately 10% of all dialysis patients had hematocrit levels that exceeded 36%, but by 2000, 40% of all dialysis patients receiving Epogen had hematocrit levels above the target amount. During that same time, there was also a significant increase in the average Epogen dose administered to dialysis patients. These increases occurred despite the fact that, in 1998, the Normal Hematocrit Study showed that there was a higher risk of death or myocardial infarction in aiming for a hematocrit level of 42%.

101. In January 2001, DaVita charted the percentages of Epogen administrations for patients with specific hematocrit levels. After outlining the percentages of distribution for particular divisions, the chart provides the "DaVita Total": 9.7% of Epogen administrations were for patients who had a hematocrit of less than 30%; 14.8% were for patients between 30 and 32.9%; 27% were for patients between 33 and 36%; and 48.5% of DaVita's Epogen administrations were for patients with hematocrit levels in excess of 36%. In other words, almost half of DaVita's Epogen administrations were for patients with hematocrit levels in excess of the target range.

102. Between 1998 and 2004, DaVita submitted claims to Medicare and was paid \$301,774,256 for Epogen administered to patients whose rolling average hematocrit levels were in excess of 37.5%. The \$301 million represented 20.08% of DaVita's Epogen charges during that seven-year period. Other for-profit facilities had a lower percentage of patients with rolling average hematocrit levels of more than 37.5%, such as DCI with 7.59%, and Fresenius with 12.90%. As previously noted, not-for-profit facilities had considerably lower percentages than DaVita or its for-profit competitors.

103. Also from 1998 to 2004, the Federal Government's Medicare program paid \$137,570,905 to DaVita for Epogen administered to patients whose rolling average

hematocrit levels were greater than 40%. The \$137 million was 9.15% of DaVita's Epogen billings to Medicare during that same period. Other for-profit facilities had a lower percentage of patients with rolling average hematocrit levels of more than 40%, such as DCI with 2.27% and Fresenius with 5.75%.

104. Administration of Epogen under these circumstances was contrary to package labeling instructions, was potentially harmful to patients, was without medical necessity or patient need, and hence constituted false claims. DaVita's increased administration of Epogen to patients with hematocrit levels above the medically-appropriate target levels occurred as part of a scheme to increase revenue. The billings constituted false claims because they were submitted with a pattern of disregard to medical necessity or patient need, contrary to package labeling instructions, and in such amounts as could be potentially harmful to patients.

**(7) DaVita's Personnel Confirmed Profit-Driven Emphasis on Increasing Epogen Administration**

105. Relator Woodard's conversations with DaVita's clinic administrators and nursing staff further confirm DaVita's over-administration of Epogen. For example, on November 27, 2000, Woodard spoke to DaVita's director of nursing at DaVita Piedmont Dialysis Center about DaVita's coordinated efforts to "bombard" Medicare and Blue Cross/Blue Shield with claims involving patients with hematocrit levels above 39.9%. As reported to Woodard, such a coordinated claims effort would overwhelm the private and governmental insurers and force them to pay the claims, not dispute them. In that same conversation, the DON indicated that DaVita's corporate meetings focused on the revenue potential from increased Epogen administration.

106. Relator Woodard also had repeated conversations with the DON at DaVita's Piedmont Dialysis Center between January and March 2000 about their utilization rates. At that facility, 88.7% of the patients had a hematocrit of greater than 33%. Of the 97 total patients at that facility for the time period noted by the DON, Woodard was told that 47 of them had a hematocrit of greater than 37.5%. Those numbers are consistent with DaVita's national figures, which show that roughly half of its patients had a hematocrit level above the target range. The DON also indicated that she was in a DaVita-sponsored competition with other facilities to see which of DaVita's clinics could have the greatest increase in their patients' hematocrit level through increased Epogen administration. DaVita offered trips and cash prizes for the competition winners.

107. Overall, DaVita went to great lengths to create a corporate policy that focused upon maximizing the profits available from high Epogen utilization rates. As Woodard witnessed, DaVita's efforts at maximizing Epogen use were particularly obvious during its expansion with the acquisition of Renal Treatment Centers ("RTC") in November 1997. After it effectively doubled in size, DaVita worked cooperatively with Amgen to transition the RTC clinics, particularly those in the Southeast United States, to DaVita's corporate strategy of maximizing profit from Epogen use, including the increasing of target hematocrit levels related to Epogen administration. When RTC clinics were reluctant or unwilling to comply with DaVita's directives on Epogen use, senior management with DaVita and Amgen met with clinic administrators and brought those clinics into compliance with DaVita's Epogen-related objectives.

**(8) Medical Records of DaVita's Patients Confirm that DaVita Administered Epogen with Reckless Disregard for FDA Labels and CMS Guidelines**

108. Relator Woodard was provided an opportunity to have a sampling of 15 patient files reviewed for Epogen administration in order to determine whether DaVita complies with CMS guidelines and the FDA label. The files were randomly chosen from a list of patients who had at least two billing cycles with a three-month rolling average of hematocrit above 40%, and a summary of the file was provided to Woodard for review. Woodard found that DaVita disregarded not only the CMS guidelines and FDA label, but also its own protocols for the over-utilization and administration of Epogen.

109. Relator Woodard hereafter provides examples of Epogen administration that show periods of three treatment-weeks or more in which DaVita administered treatments to patients with no decreases in dosage despite the fact that the patients had hematocrit levels or 40.0% or higher. Woodard found evidence of these extreme practices in 14 of the 15 patient files that were made available for review. Such repeated treatments with no reduction of dosage demonstrate DaVita's pattern and scheme of over-use of Epogen without medical necessity and at risk to the well-being of its patients.

110. Below, Woodard also provides the number of times that each patient's average hematocrit level for the preceding three months ("three-month average") was 40.0% or greater. The 40% average was selected because such continued Epogen treatments are dramatically higher than what could be held medically necessary and/or in patients' best interests. Additionally, under current CMS guidelines and as a general rule, the Federal Government no longer pays for Epogen treatments provided to patients with a hematocrit above 39%; therefore, the selection of a 40% three-month average demonstrates DaVita's over-administration of Epogen.

111. To protect the privacy interests of the patients whose files have been reviewed, Woodard hereafter refers to the patients by their initials. Woodard is willing to provide the patients' full names and the available records to DaVita, and will tender this information to the Court under seal, if requested.

112. Patient JA received dialysis treatment from DaVita at its facility, Dialysis Systems of Hammond, in Hammond, Louisiana. During the period of March 23 to April 17, 2002, Patient JA had a hematocrit level of 40.2 to 42.0%, but DaVita administered and submitted false claims to CMS for seven consecutive Epogen treatments of 12,000 units. Patient JA's records also indicate three consecutive months in which his three-month average hematocrit level was above 40.0%.

113. Patient WC received dialysis treatment from DaVita at ACQ-Owensboro Dialysis Center in Owensboro, Kentucky. From April 24 to May 10, 2004, Patient WC received nine Epogen treatments of 8,500 units, even though his hematocrit was 41.1%. For the period of July 14 to August 9, 2004, DaVita administered and submitted false claims to CMS for 12 Epogen treatments of 3,800 units to Patient WC, despite his hematocrit level ranging from 42.0 to 42.3%. Also, Patient WC received five noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

114. Patient AD received dialysis treatment from DaVita at Hemacare Dialysis or PDI Cadieux in Detroit, Michigan. During the time period of October 5 to October 31, 2001, Patient AD had a hematocrit level of 46.5%, but DaVita provided and submitted false claims to CMS for 12 Epogen treatments. For each of the 12 Epogen administrations, Patient AD received 1,000 units of Epogen. Patient AD's records also indicate eight



noncontiguous months in which her three-month average hematocrit level was above 40.0%.

115. Patient ERG received dialysis treatment from DaVita at Dialysis Center of Anson in St. Wadeboro, North Carolina. For the period October 27 to November 22, 2004, Patient ERG had hematocrit levels ranging from 40.5 to 48.3% (increasing over the course of the treatment period). Nevertheless, DaVita administered and submitted false claims to CMS for 12 consecutive Epogen treatments of 20,000 units per treatment. Also, Patient ERG received five noncontiguous months of treatment in which her three-month average hematocrit level was above 40.0%.

116. Patient CMH received dialysis treatment from DaVita at Dialysis Care of Kannapolis South in Kannapolis, North Carolina. From March 29 to April 19, 2003, Patient CMH had a hematocrit level of 44.4 to 44.7%, yet during that period, she was administered ten treatments of Epogen. For each treatment, Patient CMH received 14,000 units of Epogen. From April 21 through May 7, 2003, Patient CMH had a hematocrit of 42.9 to 44.4%, but DaVita provided and submitted false claims to CMS for eight treatments of Epogen at 13,000 units. Additionally, Patient CMH received six noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

117. Patient JCH received dialysis treatment from DaVita at Ocala South Unit in Lady Lake, Florida. From September 28 to October 28, 2002, Patient JCH had a hematocrit level of 44.1 to 46.2%. During that period, DaVita administered and submitted false claims to CMS for 14 consecutive Epogen treatments of 8,100 units. Patient JCH's records also indicate nine noncontiguous months in which his three-month average hematocrit level was above 40.0%.

118. Patient AJL received dialysis treatment from DaVita at Hopewell Dialysis Center in Hopewell, Virginia. During the time period of September 25 to October 13, 2004, Patient AJL had a hematocrit level ranging from 42.0 to 46.8%, yet she received six consecutive administrations of Epogen. For each treatment, Patient AJL received 12,000 units of Epogen. Also, Patient AJL received three consecutive months of treatment in which her three-month average hematocrit level was above 40.0%.

119. Patient JTL received dialysis treatment from DaVita at Tomball Dialysis Center in Tomball, Texas. From May 10 to May 24, 2003, Patient JTL had a hematocrit level of 40.2 to 42.3%, but DaVita administered and submitted false claims to CMS for seven Epogen treatments of 6,000 units. In October and November 2003, Patient JTL had a hematocrit level of 41.1 to 42.6%. During that period, she received ten Epogen treatments of 9,000 units per treatment.

120. Patient ML received dialysis treatment from DaVita at Santa Ana Dialysis Center #875 in Santa Ana, California. From July 2 through July 21, 2003, Patient ML had a hematocrit of 40.2%, but DaVita administered and submitted false claims to CMS for nine consecutive Epogen treatments of 10,000 units per treatment. For the period of November 17 through December 10, 2003, Patient ML had a hematocrit of 43.2 to 44.1%, but she received ten Epogen treatments of 4,000 units per treatment. Similarly, from April 24 to May 22, 2004, Patient ML had a hematocrit level of 41.1 to 43.5%. During that period, she received 13 treatments of 6,000 units per treatment. Additionally, Patient ML received five noncontiguous months of treatment in which her three-month average hematocrit level was above 40.0%.

121. Patient MML received dialysis treatment from DaVita at Grand Blanc Dialysis Center #156 in Grand Blanc, Michigan. For the period of July 17 to August 4, 2004, Patient MML had a hematocrit level of 41.7 to 43.2% (increasing throughout the treatment period). During that interval, she received nine Epogen treatments of 6,000 units per treatment. From August 7 through September 6, 2004, Patient MML had a hematocrit level of 41.7 to 44.7%. For that period, Patient MML received 14 Epogen treatments of 5,400 units per treatment. Additionally, Patient MML received six consecutive months of treatment in which her three-month average hematocrit level was above 40.0%.

122. Patient ML received dialysis treatment from DaVita at Loma Vista Dialysis Center in El Paso, Texas. From November 15 to December 3, 2003, Patient RL had a hematocrit level of 42.3 to 44.1%. During that period, DaVita administered and submitted false claims to CMS for nine Epogen treatments of 10,000 units. As an aside, the same treatment continued for six additional administrations after Patient RL's hematocrit level decreased to 39.9%. From March 27 to April 28, 2004, Patient RL had a hematocrit of 43.5 to 45.0% (increasing throughout this period), but she received 15 Epogen treatments of 2,800 units per treatment. Patient RL received seven consecutive months of treatment in which her three-month average hematocrit level was above 40.0%.

123. Patient FM received dialysis treatment from DaVita at Complete Dialysis North in Coral Springs, Florida. From November 22 to December 15, 2003, Patient FM had a hematocrit level of 41.1 to 45.3% (increasing during the treatment period). During that period, DaVita administered and submitted false claims to CMS for 11 Epogen treatments of 1,000 units per treatment. From December 17, 2003 through May 5, 2004, Patient FM received 55 Epogen treatments even though his hematocrit was always

between 40.8 and 45.3%. During that four-and-a-half month period, DaVita never withheld or reduced a treatment. Also, Patient FM received 11 noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

124. Patient EMR received dialysis treatment from DaVita at Medcenter Dialysis Center #917 in Houston, Texas. From April 21 to May 26, 2003, Patient EMR had a hematocrit level of 40.2 to 42.0%, but DaVita administered 15 Epogen treatments of 1,800 units per treatment. For the period of February 25 through March 22, 2004, Patient EMR had a hematocrit level of 44.1 to 44.7%, but he received 12 consecutive treatments of Epogen at 5,600 units per treatment. From July 24 through August 9, 2004, Patient EMR had a hematocrit level of 40.2 to 41.1%, but DaVita administered and submitted false claims to CMS for eight Epogen treatments at 10,000 units per treatment. From August 11 through September 20, 2004, Patient EMR had a hematocrit level ranging from 41.1 to 44.1 %, but he received 18 Epogen treatments at 7,500 units per treatment. Also, Patient EMR received 19 noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

125. Patient RR received dialysis treatment from DaVita at Peninsula Dialysis Center in Newport News, Virginia. From March 3 to April 7, 2004, Patient RR had hematocrit levels from 40.8 to 43.8% (increasing throughout the treatment period). During that time, DaVita administered and submitted false claims to CMS for 17 Epogen treatments to Patient RR with 6,500 units in each treatment. Additionally, Patient RR received two consecutive months of treatment in which his three-month average hematocrit level was above 40.0%.

126. Patient TES received dialysis treatment from DaVita at Dialysis Care of Rowan County in Salisbury, North Carolina. Patient TES received 15 noncontiguous months of treatment in which his three-month average hematocrit level was above 40.0%.

127. For each of the patients referenced above, CMS guidelines and FDA label indications dictate that Epogen administration should have been reduced or held because the target hematocrit level of 36% had been greatly exceeded. In each of these cases, however, DaVita administered the Epogen without reductions. Without regard to medical necessity or patient need, DaVita submitted false claims to the Federal Government for its repeated treatment of these patients and received payment based on its fraudulent charges. These randomly sampled patient files, which were from different regions and treatment periods, demonstrate DaVita's systematic, nationwide pattern of over-utilization of Epogen without regard to medical necessity or patient need.

**G. DaVita's Receipt of Discounts Based on the Volume of Purchases**

128. Amgen incentivized DaVita's clinics to overutilize Epogen because the drug got progressively less expensive—thereby increasing DaVita's profit margin on the drug—with an increased volume of Epogen purchases. The combination of volume and performance discounts (and the “free” product through overfills, as previously addressed) made Epogen one of the most profitable, if not the most profitable, revenue sources in DaVita's facilities.

129. DaVita's clinics received substantial discounts off the Average Wholesale Price (“AWP”). A price history “cheat sheet” from 1995 indicates that the Wholesale Acquisition Price (“WAP”) was calculated based on a 20% reduction from the AWP.

DaVita paid Amgen for its Epogen at or below the discounted WAP, but DaVita based its charges to the Federal Government on the AWP.

130. Additional discounts for DaVita included: (1) a fixed 7% discount off the WAP; (2) an optional Hematocrit/Hemoglobin Incentive of up to 1% based on the percentage of patients maintaining a hematocrit level of greater than 33% (paid after the fact as a refund rather than as a pricing discount); (3) a 1% Electronic Data Discount for electronic payment; and (4) "Volume Performance Discounts" up to 5.5% on sliding scale for purchases over \$184,800/year. The discounts increased in small increments (around \$1,500 for each category), and thus, DaVita's clinics were able to see tangible increases in their discounts with their increased administration of Epogen.

131. The total possible discounts totaled 14.5% off the listed WAP, which itself was heavily discounted off the AWP. These discounts were the basis for enticing clinics into over-utilizing Epogen. The discounts set up a substantial spread between the clinics' purchase price and reimbursement rate. This spread, which was increased by higher usage, then motivated the clinics to allow, develop, and encourage the manipulative practices described herein.

132. Having worked with many of DaVita's clinics and having taken their orders as an Amgen sales representative, Woodard is aware of these levels of discount. For example, Woodard witnessed such discounting practices from January 1, 2000 through September 2001 in the DaVita Piedmont Dialysis Center in Atlanta, Georgia. Also, based on his routine conversations with DaVita's directors of nursing, anemia managers, and/or clinic directors about the price discounts and rebates, Woodard is aware that DaVita did not pass on the discounts or reduced billing to its patients, nor did it pass the discounts

along to the Federal Government as required by applicable regulations. Instead, DaVita regarded the Amgen discounts as a source of additional profit. Setting aside Woodard's general knowledge based on his frequent exposure to DaVita's practices in the eight states in which he visited DaVita's clinics, Woodard remembers specifically discussing the increasing of Epogen sales to maximize available discounts or rebates at the following locations:

- a. From approximately 1992 to June 1996 at DaVita Lufkin Dialysis Center in Lufkin, Texas;
- b. From roughly 1993 to June 1996 at DaVita Livingston Dialysis Center in Livingston, Texas;
- c. In the spring of 1996 at DaVita Cleveland Dialysis Center in Cleveland, Texas;
- d. From approximately June 1996 through December 1999 at DaVita Atlanta Dialysis in Atlanta, Georgia;
- e. From roughly 1997 through 1999 at DaVita Atlanta West Dialysis;
- f. From about June 1996 through December 1999 at DaVita Buckhead Dialysis in Atlanta, Georgia; and
- g. From approximately June 1996 through December 1999 in several DaVita dialysis facilities in Miami, Orlando and Ocoee, Florida.

133. Other Amgen representatives have provided similar accounts about the discounts and rebates received by DaVita for Epogen purchases. For example, an Amgen sales representative at DaVita's dialysis centers in Dunedin and Largo, Florida from 1993 through 2002 reports that DaVita clinics received a rebate for increasing the number of its

patients that had hematocrit levels that were, at least, in the acceptable range of 33% to 36%. Similarly, one of Amgen's corporate account managers in New York, on a quarterly basis from 2003 to 2005, delivered rebate checks that were customarily in the range of five-figures to DaVita's regional vice presidents. Additionally, a clinical support specialist, who worked the gulf coast region from January 2000 through 2003 and negotiated the early stage of several contracts with dialysis centers, has corroborated that Amgen had different tiers of discounts available to customers based on the amount of Epogen purchased by the clinic.

134. DaVita acknowledged the significance and impact of these discounts in its 2005 annual report: "our agreement with Amgen for the purchase of EPO [epoetin] includes volume discount and other thresholds which could negatively impact our earnings if we are unable to meet these thresholds." This statement indicates that the savings associated with the bulk purchase and over-utilization of Epogen resulted in earnings to the company, not savings to the Federal Government as required under 42 U.S.C. § 1320a-7b.

#### **H. DaVita's Receipt of Financial Benefits in Addition to Discounts**

135. As previously noted, in 1996, Amgen began providing "anemia management training" and support to DaVita's staff in return for using Epogen. Such training provided continuing education credits (as much as eight hours of credit for each attending staff person, depending on the length of the seminar) that DaVita's nursing staff were required to obtain in order to maintain their registered nursing licenses. As addressed previously in Section IV.F.3.a. (paragraphs 68 to 70), training topics often focused on the "proper" criteria to employ to determine Epogen usage – of course, such criteria were purposefully



aimed at increasing Epogen dosage. In the process, DaVita saved substantial amounts of money that it otherwise would have spent on the training of its employees to maintain their licenses. If Amgen's seminars could be compared to the most cost-effective seminars now available, the value to DaVita was at least \$10 for each credit hour provided to DaVita's nursing staff. In actuality, the cost to Amgen was significantly greater. Amgen incurred the administrative costs for such seminars, including the fee for a hotel conference room. In addition to providing its clinical support specialists as speakers, Amgen paid for medical directors at other dialysis clinics to travel to the seminar locations and speak on topics relevant to their field. To set up such seminars, Amgen paid the speakers/doctors' honorariums (which were approximately \$750 to \$2,000), airfare (often first class at the doctor's request), car services, hotel rooms, and meals. In return, the nephrologists provided lectures and then met afterward (usually the next day) with DaVita's local clinic administrators and medical directors. In addition to providing valuable and necessary training to DaVita's staff, Amgen used the platform to advocate its business model of maximizing Epogen usage for profit to both DaVita and Amgen.

136. In addition to providing training for DaVita's staff, Amgen also paid educational grants to DaVita's medical directors, clinic administrators, directors of nursing, nursing staff, and even social workers. Customarily, these educational grants were given because of specific grant requests made by DaVita's personnel. Amgen's educational grants varied in amount, ranging from \$250 to \$5,000. Woodard provided such grants so that DaVita's medical directors, clinic administrators, and DONs could attend seminars with the National Kidney Foundation, the National Renal Administrators Association, the American Nephrology Nurses Association, and other professional organizations. For

example, in January 2001, Piedmont's medical director expressed his appreciation for the grants, but as often occurred, he made a request for additional funds. From the medical director, Amgen's grants extended throughout the ranks of DaVita's personnel; for example, in approximately December 2000, Woodard provided an educational grant of roughly \$500 to a social worker at DaVita Piedmont. From Amgen's perspective, the grants garnered favor and increased the likelihood that Amgen would be afforded opportunities to draft protocols, to conduct chart reviews, and to otherwise influence DaVita's practices of Epogen administration. Meanwhile, such grants provided a direct financial benefit to DaVita, which otherwise would have paid for such seminars. It is Woodard's understanding that DaVita did not disclose its receipt of such grants to the Federal Government.

## **V. CAUSES OF ACTION**

### **A. Count One: Fraudulent Overcharge for Captured Overfill**

137. The allegations of Paragraphs 1 through 136 are incorporated herein by reference. The facts and circumstances demonstrate DaVita's scheme of submitting false claims to the Federal Government and its large volume of Epogen sales arising from the wrongful practices.

138. DaVita submitted a substantial volume of false claims to Medicare based on its charges for captured overfill. DaVita received the "captured" medication from distributors free of charge but then billed the Federal Government as if DaVita paid for it in full. Such conduct constituted a knowing violation of the terms for payment by the Federal Government. The Centers for Medicare and Medicaid Services ("CMS") recently published a proposed rule (which is quoted at length in paragraph 19 above) and noted

CMS' "longstanding policy" that the cost of medication must be an actual expense to the healthcare provider in order for it to be entitled to payment for that medicine from the Federal Government. Quite simply, DaVita's conduct of billing for Epogen overfill was fraudulent and improper.

139. In addition to the wrongful conduct of charging the Federal Government for medicine that DaVita had received at no cost, DaVita further violated federal regulations by endangering its patients with the pooling of preservative-free medication. DaVita's re-entry into single use vials was contrary to the requirement that it safely administer its services. Like other governmental providers of healthcare coverage, Medicare does not pay for medical care that is not "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A) (often referred to as section 1862(a)(1)(A)). Similarly, federal regulations dictate that DaVita must comply with "relevant health and safety requirements." 42 C.F.R. § 405.2135. DaVita's administration of Epogen overfill was contraindicated by the drug's labeling and also contrary to what is considered good medical practice according to relevant medical and scientific studies. Making multiple entries into single dose vials to extract overfill was inconsistent with good medical practice, because it was contrary to the FDA label, increased the risk of infection, and therefore was not "safe." Aware of these facts, DaVita nevertheless wrongly pooled and administered free overfill, and thereby submitted millions of dollars of claims for its improper administration of the medication. Such conduct violated the Medicare Benefit Policy Manual, 50.4.1, which requires that the "[u]se of the drug . . . must be safe . . . ." The Medicare Benefit Policy Manual (in section 50.4.3.3) dictates that the government should not pay for DaVita's misuse of Epogen: "If medication is determined not to be reasonable

and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the carrier excludes the entire charge.”

140. DaVita violated 31 U.S.C. § 3729 in that it knowingly submitted claims for Epogen administered as described above, even though by doing so they were not in compliance with Federal, state, and local laws and regulations, nor were they using the drug consistent with its label or good medical practice, both of which were conditions for reimbursement.

141. By billing for medication in a manner that was inconsistent with its package insert, by billing for overfill medication, and by billing the Federal Government for more medication than was actually administered to patients, DaVita knowingly submitted false claims for Epogen and violated 31 U.S.C. § 3729. By doing so, DaVita violated conditions for governmental reimbursement because it was not in compliance with Federal, state, and local laws and regulations. In addition to identifying the basic nature, framework, and procedures underlying DaVita’s fraudulent scheme, Woodard has addressed specific instances of fraud based on DaVita’s administration of more Epogen than it had in its inventory. Woodard will identify additional, specific instances of fraud after engaging in discovery and receiving information under the exclusive control of DaVita.

142. DaVita’s submission of false claims, in turn, caused the Federal Government to pay DaVita for claims either based on false certifications that DaVita had complied with all applicable laws or for which DaVita was not entitled to be paid. The United States, unaware of the falsity of the claims and/or statements made by DaVita, and in reliance on the accuracy of DaVita’s claims and statements, paid for Epogen by the federally-funded health insurance programs, including Medicare. If the United States had known that the

bills presented by DaVita for payment were false, misleading, and fraudulent, payment would not have been made for such claims. The result was injury to the United States Treasury from paying DaVita's medical claims that otherwise would not have been paid.

**B. Count Two: Fraudulent Over-Administration of Epogen**

143. The allegations of Paragraphs 1 through 142 are hereby incorporated by reference. The facts and circumstances demonstrate DaVita's scheme of submitting false claims and its large volume of Epogen sales arising from the wrongful practices.

144. In violation of 31 U.S.C. § 3729(a)(1), Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States. Alternatively, the Defendant presented or caused to be presented such claims with reckless disregard or deliberate ignorance of their truth or falsity.

145. DaVita violated 31 U.S.C. § 3729 in that it knowingly submitted claims for Epogen administered without regard to medical necessity or patient need as described above, and by doing so, it was not in compliance with Federal, state, and local laws and regulations, nor was it using the drug consistent with its label or good medical practice, both of which are conditions for reimbursement by the Federal Government.

146. Like other governmental providers of healthcare coverage, Medicare does not pay for medical care that is not "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. 1395y(a)(1)(A) (often referred to as section 1862(a)(1)(A)). Similarly, section 494.20 provides: "[An ESRD facility and staff] must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements." 42 C.F.R. § 494.20. Section 405.2135 also dictates that there must be

compliance with "relevant health and safety requirements." 42 C.F.R. § 405.2135. DaVita's overutilization of Epogen for patients with hematocrit levels above 40% was unnecessary, unsafe, and against the best interests of DaVita's patients. Further, the regulations reiterate that DaVita was required to be in compliance with federal regulations and laws, such as those in 42 U.S.C. § 1395y(a)(1)(A) and 42 C.F.R. § 411.15 (and addressed further below).

147. DaVita's overutilization of Epogen was contraindicated by the drug's labeling and also contrary to what is considered good medical practice according to relevant medical and scientific studies. Such conduct violated the Medicare Benefit Policy Manual, 50.4.1, which requires that the "[u]se of the drug . . . must be safe . . . ." Aware of these facts, DaVita nevertheless over-prescribed the drug and thereby submitted millions of dollars of claims for its unwarranted administration of the medication. The Medicare Benefit Policy Manual (in section 50.4.3.3) dictates that the government should not pay for DaVita's misuse of Epogen: "If medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the carrier excludes the entire charge." Therefore, through procedures, practices, and/or protocols intended to result in the over-administration and over-utilization of Epogen without regard to guidelines for hematocrit level and without regard to medical necessity or patient need, DaVita knowingly submitted false claims for Epogen to the Federal Government.

148. DaVita violated 31 U.S.C. § 3729 in that it knowingly submitted claims for Epogen administered without regard to medical necessity or patient need. DaVita violated conditions for reimbursement by the Federal Government, because it was not in

compliance with Federal, state, and local laws and regulations, and it was not using Epogen consistent with its label or good medical practice. In addition to identifying the basic nature, framework, and procedures underlying DaVita's fraudulent scheme, Woodard has addressed specific instances of fraud from a random sampling of patient files. Woodard will identify additional, specific instances of fraud after engaging in discovery and receiving information under the exclusive control of DaVita.

149. DaVita's submission of false claims, in turn, caused the Federal Government to pay DaVita for medical claims based on false certifications that DaVita had complied with all applicable laws or because DaVita should not have been paid for the administration of Epogen under the circumstances. This resulted in financial injury to the United States Treasury from paying claims that otherwise should not have been paid because they were fraudulently procured and unnecessary.

**C. Count Three: DaVita Violated the Fraud and Abuse Statutes by Not Disclosing Discounts and Other Remuneration Arising From its Epogen Purchases**

150. The allegations of Paragraphs 1 through 149 are incorporated herein by reference.

151. DaVita knowingly submitted false claims to the Federal Government for reimbursement of Epogen in that it received prohibited remuneration (in the form of discounts, rebates, and in-kind kickbacks) in return for purchasing Epogen, while falsely certifying to the Federal Government that it was in compliance with all applicable laws and regulations.

152. As noted above, compliance with all applicable laws and regulations is a condition of coverage for the Federal Government's reimbursement of dialysis treatments. 42 C.F.R. § 405.2135; 42 C.F.R. § 494.20.

153. DaVita violated 42 U.S.C. §§ 1320a-7a & 7b in that:

- a. DaVita purchased Epogen from Amgen at a reduced, rebated price;
- b. DaVita failed to disclose or pass on the discounts and rebates to the Federal Government, either in its bills for Epogen or in HCFA-265;
- c. The undisclosed discounts and rebates constituted prohibited remuneration under 42 U.S.C. §§ 1320a-7a & 7b, because the discounts and rebates were paid by Amgen in exchange for DaVita's purchase of Epogen, which was then reimbursed by the Federal Government.

154. DaVita also violated 42 U.S.C. §§ 1320a-7a & 7b in that:

- a. Amgen provided anemia management training and support to DaVita's staff. Amgen provided this service free of charge to DaVita and thereby saved it substantial training expenditures each year;
- b. The anemia management training that Amgen provided to DaVita constituted prohibited in-kind remuneration under 42 U.S.C. §§ 1320a-7a & 7b because it was provided in exchange for DaVita's purchase of Epogen, which was then reimbursed by the Federal Government.

155. DaVita violated 42 U.S.C. §§ 1320a-7a & 7b in that:

- a. DaVita received and administered overfill as "free" product;
- b. DaVita failed to disclose or pass on the savings associated with the administration of overfill to the Federal Government, either in its bills for Epogen or in compliance with HCFA-265;
- c. The undisclosed savings resulting from the administration of overfill constituted prohibited remuneration under 42 U.S.C. §§ 1320a-7a & 7b, because the "free"



product was provided by Amgen in exchange for DaVita's purchase of Epogen, which was then reimbursed by the Federal Government.

156. Because DaVita falsely certified that it was in compliance with Federal, state and local laws and regulations when in fact it was violating 42 U.S.C. §§ 1320a-7a & 7b, and because such certification was a condition of coverage, DaVita violated 31 U.S.C. § 3729 by knowingly submitting false claims for Epogen to the Federal Government.

157. In return for making these misrepresentations to the Federal Government, DaVita rewarded itself with higher profits in the form of volume discounts, rebates, and kickbacks from Amgen as well as the profit on Epogen that it administered without a sound medical basis for doing so. The United States Treasury has been financially damaged by DaVita's wrongful withholding of its savings and undue profit.

**D. Count Four: DaVita Submitted False Cost Reports**

158. The allegations of Paragraphs 1 through 157 are hereby incorporated by reference. The facts and circumstances demonstrate DaVita's scheme of submitting false claims and its large volume of Epogen sales arising from the wrongful practices.

159. Each year, DaVita submitted a cost report known as HCFA-265 to the Health Care Finance Administration. HCFA-265 was required from all dialysis facilities that bill to the Federal Government and included a certification of DaVita's adherence to federal laws and regulations. The tender of cost data and the certification in HCFA-265 were conditions of coverage. 42 C.F.R. § 405.2138; 42 C.F.R. § 494.180(h)(3).

160. Defendant falsely certified its compliance with federal, state, and local laws and regulations, and because such certification was a condition of coverage by Medicare,

Defendant violated 31 U.S.C. § 3729(a)(2) in that it knowingly submitted false claims to Medicare.

## **VI. PRAYER**

WHEREFORE Relator, Ivey Woodard, prays that this Court:

(1) Assess a civil penalty of not less than \$5,500 and not more than \$11,000 against DaVita, Inc., as provided by 31 U.S.C. § 3729(a), for each and every false claim as a result of its charges to the Federal Government for the administration of Epogen in violation of applicable FDA label and CMS guidelines;

(2) Assess a civil penalty of not less than \$5,500 and not more than \$11,000 against DaVita, Inc., as provided by 31 U.S.C. § 3729(a), for each and every false claim as a result of its charges to the Federal Government for the administration of Epogen from overfill;

(3) Assess a civil penalty of not less than \$5,500 and not more than \$11,000 against DaVita, Inc., as provided by 31 U.S.C. § 3729(a), for each and every false claim as a result of its charges to the Federal Government without disclosure of remuneration and discounts that DaVita had received from Amgen;

(4) Award damages in the sum of three times the amount fraudulently billed to the Federal Government as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

(5) Award him reasonable expenses, attorney's fees and costs, as provided by 31 U.S.C. § 3730(d);

(6) Exclude DaVita, Inc. from participation in all Federal healthcare programs;  
and

(7) For such other and further relief as this Court deems just and proper.

**JURY TRIAL DEMAND**

Relator hereby demands a jury trial.

Dated: December 1, 2010.

By: /s/ Mitchell A. Toups

Mitchell A. Toups  
Steven Toups  
WELLER, GREEN, TOUPS & TERRELL  
2615 Calder Street, Suite 400  
P.O. Box 350  
Beaumont, TX 77704-0350  
409/838-0101  
409/838-6780 Facsimile

Michael A. Caddell  
Cynthia B. Chapman  
John B. Scofield, Jr.  
Craig C. Marchiando  
CADDELL & CHAPMAN  
1331 Lamar, Suite 1070  
Houston, TX 77010  
713/751-0400  
713/751-0906 Facsimile

David A. Burkhalter, II  
BURKHALTER, RAYSON & ASSOCIATES  
111 S. Central Street, P.O. Box 2777  
Knoxville, TN 37901  
856/524-4974  
856/524-0172 Facsimile

Scott R. Shepherd  
SHEPHERD, FINKELMAN, MILLER  
& SHAH, LLC  
35 E. State Street  
Media, PA 19063  
610/891-9880  
610/891-9883 Facsimile

**ATTORNEYS FOR RELATOR**

**CERTIFICATE OF SERVICE**

I certify that, pursuant to the terms and requirements of the United States False Claims Act, 31 U.S.C. § 3730(b)(2) and Federal Rule of Civil Procedure 4(d)(4), true and correct copies of the foregoing were served on all counsel identified below by certified mail, return receipt requested on this 1st day of December, 2010:

Eric Holder  
United States Attorney General  
U.S. Department of Justice  
10th & Constitution Avenues, N.W.  
Washington, D.C. 20530

Mark W. Pearlstein  
McDermott Well & Emery, LLP  
28 State Street  
Boston, MA 02109-1775

John Bales  
U.S. Attorney  
Eastern District of Texas  
350 Magnolia Street, Suite 150  
Beaumont, TX 77701-2237

Thad Heartfield  
Dru Montgomery  
The Heartfield Law Firm  
2195 Dowlen Road  
Beaumont, Texas 77706

/s/ Mitchell A. Toups  
Mitchell A. Toups